DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2015

YTY Industry (MANJUNG) SDN. BHD.
Mr. Andrew Lowery
Official Correspondent
QA/GMP Consultant
14004 Manor Road, P O Box 445
Phoenix, Maryland 21131

Re: K142283
Trade/Device Name: Non-Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H), Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color]
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient examination glove
Regulatory Class: I
Product Code: LZA
Dated: December 13, 2014
Received: December 18, 2014

Dear Mr. Lowery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142283

Device Name

Non Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color]

Indications for Use *(Describe)*

The Non Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PSC Publishing Services (301) 443-6740 EF

510 (K) SUMMARY SHEETS

1.0 **510 (K) SUMMARY**

2.0 Submitter

YTY INDUSTRY (MANJUNG) SDN. BHD.,
Lot 1422-1424, Batu 10 Lekir
32020 Sitiawan, Perak
Malaysia

Tel 605-6908533

Fax 605-6908501

Name of Contact Person 1. Ms. Punitha Samy

Date Summary Prepared January 13, 2015

3.0 Name of Device

Trade Name: Non-Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color]

Common Name: Nitrile Examination Gloves

Classification Name: Patient Examination Gloves, Powder Free

Device Classification: I

Regulation Number: 21 CFR 880.6250

Panel: General Hospital (80)

Product Code: LZA

4.0 Identification of The Legally Marketed Devices

Non Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] as described in this 510k Notification is substantially equivalent to the current Class I patient examination gloves bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Gloves for Medical Application. Predicate 510(K) number for this application is K052502.

5.0 Description of The Device

Non-Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. This device is for over-the counter single use. The principle operation and mechanism of this device is to prevent contamination between patient and examiner and this principle is achieved through testing of barrier, physical properties and other testing stated in the performance data. This device is for over-the counter single use.

6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This device is for over-the counter use.

7.0 Summary of Performance Data:

There is no difference in technology characteristic compared to the predicate device. Gloves are made from nitrile latex compound. Non-sterile, Powder Free Nitrile Examination [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] Gloves have the below technological characteristic compared to ASTM or Equivalent standards.

Characteristic	Standards	Performance of Non-Sterile, Powder Free Nitrile Examination Gloves
Dimension	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10	Meets
Freedom from holes	ASTM D6319-10	Meets
Powder-free	ASTM D6319-10	Meets
Bio-compatibility	Primary skin irritation ISO 10993-10	Non-Irritant
	Dermal Sensitization ISO 10993-10	Non-sensitizer

Performance data of gloves based on ASTM D6319-10 and FDA 1000ML water leak test.

Test	**FDA 1000ml Water Leak Test**	YTY Powder Free Nitrile Examination Gloves							
1. Watertight (1000ml) ASTM D5151-06 (2011)	Multiple Normal GII AQL = 2.5 Lot size: 16,000 Sample Size: 80	Blue 8603F (AD)	Blue 8611F (M)	Blue 8603F (Y4)	Blue 8613F	Blue 8603 (H)	Blue 8612F (C)	Black 8604T	White 8617F
		Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)	Holes found: 0 (Accept 5, Reject 6)
Test ASTM D6319-10	ASTM D6319-10								
2. Length (mm) Size M	Min 230	240-247	240-248	241-247	244-252	240-247	247-253	245-253	245-253
3. Palm width (mm) Size M	95 ± 10	95-97	97-99	95-97	95-99	95-97	96-97	96-99	96-98
4. Thickness (mm) (Single Layer)									
Finger	Min 0.05	0.10-0.12	0.09-0.11	0.10-0.12	0.09-0.12	0.11-0.14	0.08-0.10	0.13-0.16	0.10-0.12
Palm	Min 0.05	0.07-0.08	0.06-0.07	0.06-0.07	0.06	0.06-0.07	0.06-0.07	0.10-0.12	0.06-0.08
5. Physical Properties									
Before Aging									
Tensile Strength (MPa)	Min 14	25.90-32.06	25.59-31.07	25.09-30.66	23.14-29.50	23.33-29.02	24.64-28.78	20.51-23.75	22.70-29.88
Ultimate Elongation (%)	Min 500	540-580	560-600	580-600	520-560	520-540	560-600	540-560	540-580
After Aging									
Tensile Strength (MPa)	Min 14	28.40-33.92	26.54-32.19	30.72-37.60	26.53-33.17	28.04-33.98	24.14-28.78	23.81-31.78	23.90-31.77
Ultimate Elongation (%)	Min 400	460-500	480-520	500-540	460-500	480-500	560-600	460-520	460-520
6. Moisture Content (%)	Max 2.0%	0.99% Average	1.1% Average	1.0% Average	1.0% Average	1.2% Average	1.1% Average	0.8% Average	1.0% Average
7. Residual Powder ASTM-D6124-10 (Reapproved 2011)	Max 2.0mg/ glove	0.20mg/ glove	0.12mg/ glove	0.10mg/ glove	0.14mg/ glove	0.16mg/ glove	0.16mg/ glove	0.16mg/ glove	0.14mg/ glove
8. Biocompatibility Primary Skin Irritation Dermal Sensitization	ISO 10993-10 Non-irritant Non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer	Under the conditions of the study, the device is non-irritant or non-sensitizer

8.0 Substantial Equivalence Comparison Table with Predicate Device, K052502

Characteristics	K142283								Predicate K052502	Medical Glove Manual (1661)
	Blue Glove 8603F (AD)	Blue Glove 8611F (M)	Blue Glove 8603F (Y4)	Blue Glove 8613F	Blue Glove 8603 (H)	Blue Glove 8612F (C)	Black Glove 8604T	White Glove 8617F		
Company Name	YTY Industry (Manjung) Sdn Bhd								YTY Industry (Manjung) Sdn Bhd	FDA
Product Name	Non-sterile, Powder Free Nitrile Examination [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C)Blue Color, 8604T Black Color and 8617F White Color]								Non-Sterile, On Line Powder Free Nitrile Blue & White Color Examination Gloves	Patient Examination Gloves
Product Code	LZA								LZA	LZA – (Polymer – other than Vinyl (includes Nitrile, Polyurethane, etc.)
Indication for Use	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.								This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.	**Powder-Free Examination Gloves** A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Device Description	Non Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] meets all the current specifications listed under the ASTM Specification D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. This device is for over-the counter single use.								Class 1 Nitrile Patient Examination Glove 80 LZA, powder free that meets all requirements of ASTM Standard D6319-00a$^{\varepsilon 3}$ and FDA water leak test.	This gloves meet all current specifications listed under ASTM specifications D6319-10
Over the Counter Use	This device is for over-the counter single use.								This device is for over-the counter single use.	Indication for use
Single Use	Single Use								Single Use	Misbranding
Non Sterile or Sterile	Non Sterile								Non Sterile	Sterilization
Powder Free	Powder Free								Powder Free	Process & Attribute labeling
Compare materials										
Materials	Carboxylated Butadiene Acrylonitrile								Carboxylated Butadiene Acrylonitrile	LZA – (Polymer – other than Vinyl (includes Nitrile, Polyurethane, etc.)

Characteristics	K142283								Predicate K052502	Medical Glove Manual (1661)
	Blue Glove 8603F (AD)	Blue Glove 8611F (M)	Blue Glove 8603F (Y4)	Blue Glove 8613F	Blue Glove 8603 (H)	Blue Glove 8612F (C)	Black Gloves 8604T	White Gloves 8617F		
Specifications and Performance										
Tensile Strength before aging (MPa)	25-59-31.07	25.59-31.07	25.09-30.66	23.14-29.50	23.33-29.02	24.64-28.78	20.51-23.75	22.70-29.88	26.00-30.00	Current gloves meet ASTM D6319-10 Nitrile gloves ASTM D6124-06 (Reapproved 2011) Residual Powder ASTM D5151-06 (Reapproved 2011) Detection of Holes in Medical Gloves
Tensile Strength after aging (MPa)	28.40-33.92	26.54-32.19	30.72-37.60	26.53-33.17	28.04-33.98	24.14-28.78	23.81-31.78	23.90-31.77	25.00-28.00	
Ultimate Elongation before aging (%)	540-580	560-600	580-600	520-560	520-540	560-600	540-560	540-580	750-800	
Ultimate Elongation after aging (%)	460-500	480-520	500-540	460-500	480-500	560-600	460-520	460-520	670-730	
Dimensions Length (mm)	240-247	240-248	241-247	244-252	240-247	247-253	245-253	245-253	240-251	
Dimensions Width (mm)	95-97	97-99	95-97	95-99	95-97	96-97	96-99	96-98	94-96	
Thickness Finger (mm)	0.10-0.12	0.09-0.11	0.10-0.12	0.09-0.12	0.11-0.14	0.08-0.10	0.13-0.16	0.10-0.12	0.15-0.19	
Thickness Palm (mm)	0.07-0.08	0.06-0.07	0.06-0.07	0.06	0.06-0.07	0.06-0.07	0.10-0.12	0.06-0.08	0.12-0.16	
AQL (As per FDA requirement)	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	Multiple Normal Sampling GII AQL 2.5 Lot size: 16,000 Sample Size: 80 Acc: 5 Rej: 6 Result: 0	
Residual Powder (mg/glove)	0.99% Average	1.1% Avg.	1.0% Avg.	1.0% Avg.	1.2% Avg.	1.1% Avg.	0.8% Avg.	1.0% Avg.	0.20% Avg.	
Size		M	M	M	M	M	M	M	M	

Characteristics	K142283								Predicate K052502	Medical Glove Manual (1661)
	Blue Glove 8603F (AD)	Blue Glove 8611F (M)	Blue Glove 8603F (Y4)	Blue Glove 8613F	Blue Glove 8603 (H)	Blue Glove 8612F (C)	Black Gloves 8604T	White Gloves 8617F		
Biocompatibility	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Under the condition of the study the device is non-irritant and non-sensitizer	Non-irritant Non-sensitizer	ISO 10993-10 Skin Irritant Dermal and Sensitization studies
Labeling for legally marketed predicate	-Powder Free -devices color -Patient Examination Glove -Non sterile -Single Use Only - Manufactured For: - Lot - Intended use								-Powder Free -devices color: Clear(Blue) -Patient Examination Glove -Non sterile -Single Use Only - Manufactured For: - Lot	Chapter 4 - Labeling

9.0 Summary of the Technological Characteristic of the Device compared to the Predicate Device for substantial equivalent discussion

There is no difference in technology characteristic compared to the predicate device. Gloves are made from nitrile latex compound. Non-Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] have the above technological characteristic compared to ASTM or Equivalent standards.

10.0 Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the device, Non-Sterile, Powder Free Nitrile Examination Gloves [(8603F (AD) Blue Color, 8611F (M) Blue Color, 8603F (Y4) Blue Color, 8613F Blue Color, 8603F (H) Blue Color, 8612F (C) Blue Color, 8604T Black Color and 8617F White Color] and the predicate device is substantially equivalent based on intended uses, physical properties, technological characteristics and non-clinical performance. This device is safe, effective, and performs as well as the predicate device.